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EXAMINER	
LEAVITT, MARIA GOMEZ	

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1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,098	GOLETZ ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,9-12,20 and 22* is/are pending in the application.

4a) Of the above claim(s) *7, 9, 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,11,12,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07-09-08;06-07-06;02-10-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Applicant's election of Group I, drawn to a cell line which expresses on the cell surface TF, MUC1 and glycophorin and a method of using the cell, namely claims 1, 3, 5, 6, 11 (in part), 12 (in part), 20 (in part) and 22 (in part), in the response filed on 08-19-2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In response to the species election, applicant's election **with traverse** of lymphoma as the type of cancer is acknowledged.

Response to Applicant's argument

Applicant's arguments in view of the official restriction/election requirements of May 09, 2008 have been respectfully reconsidered but have been found unpersuasive. Applicant's traversal is that the species restriction in not clear and too extensive, that a search of prior art would be overlapped, and the there is no undue burden to do a search of all the species as listed in the claims. Specifically, applicants argue that treatment or prevention of any of the types of cancer species recited in claim 22 does not require a unique special technical feature not shared by other species, because no unique method of practicing the invention is required for any of the recited cancers. Such is not persuasive.

Though the treatment and/or prevention of any of the recited types of cancer in claim 22 merely requires administration of a cell which expresses on the surface TF, MUC1 and glycophorin, which is the same method step for all the cancers recited, given the distinct etiologies and involvement of distinct cell types in each of the recited cancers or tumourous diseases, each will respond differently to the claimed cell composition, requiring different

search and considerations of arts relevant to the claimed species. Therefore, examination of the claimed species as a whole would be unduly burdensome. However, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR1.14. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a)

Accordingly, claims 1, 3, 5, 6, 7, 9, 10-12, 20 and 22 are pending in the instant application. Of these, claims 7, 9 and 10 are withdrawn from consideration as being directed to non-elected inventions pursuant to 37 CFR1.14(b), there being no allowable generic or linking claim.

The requirement is still deemed proper and made final.

Therefore, claims 1, 3, 5, 6, 11 (in part), 12 (in part), 20 (in part) and 22 (in part) are currently under examination to which the following grounds of rejection are applicable.

Information Disclosure Statement

The information disclosure statements filed on February 10, 2006, June 7, 2006 and July 09, 2008 have been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

The information disclosure statement filed on February 10, 2006 and July 09, 2008 fail to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references have not been considered:

Ichiyama (2000) as an English translation of the JP document has not been provided and Goletz (2003) Adv. Exp. Med. Biol., as a copy of the publication has not been provided.

All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto.

Claim Objection

Claims 1, 11 and 20 are objected to because of the following informalities: abbreviations such as TF and MUC1 should be spelled out at the first encounter in the claims. Appropriate correction is required

Claim Rejections - 35 USC § 112-Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is more nearly connected, to make and/or use the invention.

The application discloses two cell lines NM-F9 and NM-D4 that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is apparent the cell lines i.e., NM-F9 and NM-D4 generated from K562 cells (ATCC CCL-243) both of them expressing several highly specific tumour associated carbohydrate antigens, namely the Thomsen-Friedenreich antigen (TF) in very high amounts, and asialoglycophorin (AGPA) consisting of the carrier protein glycophorin and TF groups in high amounts, LeX in high amounts, TA-MUC1 in moderate amounts and Tn in comparably low amounts (p. 5, lines 27-32; p.9, lines 5-10) is required to practice the claimed invention of claim 3. Thus, this must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. §112, first paragraph, may be satisfied by a deposit of the strain.

It is unclear whether this biological material is known and readily available to the public or that the written instructions in the Specification are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material

specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office.

It is noted that the Applicants list the name of the cell line NM-F9 having the DSMZ accession number DSM ACC2606 and a cell line denominated NM-D4 having the DSMZ accession number DSM ACC2605, both deposited with the Deutsche Sammlung fur Mikroorganismen und Zellkulturen GmbH ("DSMZ") Aug. 14, 2003 and having the deposit number DSM ACC2605. Furthermore, the aforementioned DSMZ deposits were made pursuant to the terms of the Budapest treaty on the international recognition of the deposit of microorganisms for purposes of patent procedure (p. 8, lines 22-32). However, Applicant is reminded that a statement that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of a patent is also required.

Please see the deposit information below, especially the paragraph following sections 4 to 7.

A suggestion for deposit of biological materials is provided:

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. See 37 CFR 1.801 through 1.809. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent.

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977), that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the

granting of a patent, and that the deposited material will be maintained for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Additionally, claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide enablement for claims directed to methods of treating or preventing lymphoma in a subject by administering a cell line expressing TF, MUC1 and glycophorin on its surface as broadly claimed. The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Claims 20 and 22, when given the broadest possible interpretation, encompass methods for treating and or preventing any type of lymphoma e.g., mucosa-associated lymphoid tissue, B-cell lymphoma, T cell lymphoma, gastric lymphoma and others. Applicant provides in the specification sufficient description for *in vitro* validation of induction of naive cytotoxic T cells against MUC1 and AGPA expressed in functional mature dendritic cells, said dendritic cells loaded with NM-F9 lysates in a prime reaction and loaded with the MUC1 peptide and AGPA protein in a restimulation. Accordingly, Fig. 6 illustrates that naive CTL can be activated against these MUC1 and AGPA antigens by using NM-F9 lysates (page 55, lines 19-23). Moreover, the specification discloses *in vivo* induction of an IgG and IgM antibody responses in NOD/SCID mice reconstituted with human PBMC that were vaccinated with NM-F9 cell lysates, indicating induction of T helper immune responses and memory immune responses against MUC1, TF and AGPA (p. 55, lines 24-30). Furthermore, the specification teaches that NM-F9 and NM-D4 cells are more sensitive to the cytolytic activity of NK cells than K562wt because of a very low degree of sialylation on the cell surface (p. 56, lines 25-26), which is in contrast to the literature wherein sialylated carbohydrates have been described to mediate the cytotoxic lysis by NK cells (p. 58, lines 18-24). However, the specification is silent about *in vivo* administration of a cell line which expresses on the cell surface TF, MUC1 and glycophorin to treat or prevent lymphoma.

In so far as the treatment of lymphoma, the art discloses that the etiology of lymphoma is multifactorial and it is likely to involve the actions of genes at multiple levels along the

multistage carcinogenesis process. Therefore, the different types of lymphoma e.g., mucosa-associated lymphoid tissue, B-cell lymphoma, T cell lymphoma, gastric lymphoma and others require specific therapeutics. For example, patients with lymphoma of the mucosa-associated lymphoid tissue (MALT) were treated with chemotherapy by using the nucleoside analog cladribine (Jaget et al. *Journal of Clinical Oncology*, pp. 3872-3877) whereas patients with low-grade or follicular B-cell non–Hodgkin's lymphoma received a chimeric anti-CD20 antibody, Rituxan in combination with standard-dose systemic chemotherapy (Czuczman et al., *Journal of Clinical Oncology*, 1999: 268-276, Abstract). In relation to the use of anti-TF antibodies for treatment of carcinomas, the art at the effective time of filing, merely discloses the critical role of TF in the liver metastasis of tumor cells from colon carcinomas and the contemplated therapy of mediating interaction of TF with ASGPR of the hepatocytes to prevent liver metastasis (Goletz et al., 2003, Advances in experimental medicine and biology, pp. 147-62; p. 156, last paragraph). The author further contemplates TF as a tumor maker for passive and active immunotherapy (p. 159, last paragraph). Furthermore, Carbone et al., corroborates the unpredictability of a treating or preventing lymphoma as any other cancer when he states:

> "In the past 40 years, there have been great advances in our understanding of cancer at the cellular and molecular level. However, this information has been difficult to translate to the bedside, and there has been little improvement in our ability to treat advanced solid tumors, i.e, carcinomas, the most common types of human cancers. The prognosis of metastatic carcinoma of the lung, larynx, breast, prostate, pancreas, liver, etc., has not significantly changed during the past 40 years. This is partly because advanced solid tumors are genetically heterogeneous both among cases and within the same patient. They are also genetically instable (i.e., they continuously develop new genetic clones). Therefore, any new therapeutic agent identified is aiming at a "moving target" which can readily adapt to most forms of therapeutic attack."

Since each prospective embodiment for the treatment and/or prevention of different types of lymphoma, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope to treat or prevent virtually any lymphoma. The instant issue is whether or not the prior art and the as-filed application provides sufficient guidance and the degrees of predictability as to the structural and functional correlation between the administration of a cell line expressing TF, MUC1 and glycophorin on its surface to achieve a therapeutic effect in the treatment or prevention of lymphoma. A close review of the entire specification and the prior art does not appear to provide such guidance, particularly in view of the nature and complexity of treating or preventing a lymphoma. As the result, the quantity of experimentation required to practice the methods as claimed would require the de novo determination of effective target sites, modes of delivery, safe administration of a cell line which expresses on the cell surface TF, MUC1 and glycophorin to target appropriate cells and/or tissues in any type lymphoma, in a mammal, including a human, and further whereby treatment effects are provided for the widely diverse lymphomas. Without such guidance in the specification and the lack of correlative working examples, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Claim Rejections - 35 USC § 102

The following is a quotation of 35 U.S.C. 102 which forms the basis for all obviousness rejections set forth in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Ichiyama M (2000, Kari Igaku Kenkyusho Zasshi, JP vol. 51, no. 3-4, pages 93-110, of record) as evidenced by Benoist et al., (1992, Immunology Letters, pp. 45-55) and Karsten et al., (1998, Cancer Research pp. 2541-2549, of record)

Ichiyama M, discloses the cell line K562 contransfected with tumor-associated epithelial human mucin MUC1cDNA and with human B7cDNA (Figures 1-12) . Though Ichiyama M, does not explicitly teach that the cell line K562 expresses on the surface glycophorin and TF, these two antigens are inevitably and inherently present in K562 cells as evidenced by the teachings of Benoist disclosing that K562 tumor cells present glycophorin A (GPA) on the cell surface (Abstract), and the disclosure of Karsten demonstrating the presence of the TF antigen (Thomsen-Friedenreich antigen) within the immunodominat region of the MUC1 repeats (p. 2541, col. 2, paragraphs 1-2). Note that claim 1 does not place any limitation on the specific location of TF , it only requires for TF to be on the surface of the cell line. As TF is located on the MUC1 repeats and MUC1 is located on the surface of K562, it follows that TF is on the surface of K562, absent evidence to the contrary.

Thus by teaching all the claims limitations, Ichiyama M et al., anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6, 11 and 12 are rejected under 35 USC 103 as being unpatentable over Ichiyama M (2000, Kari Igaku Kenkyusho Zasshi, JP vol. 51, no. 3-4, pages 93-110, of record) in view of Benoist et al., (Immunology Letters 1992, pp. 45-55) and Karsten et al., (1998, Cancer Research pp. 2541-2549, of record) and further in view Horton et al., (U.S. Patent 7,268,120, Date of filing Apr. 21 2000).

Ichiyama M, discloses the cell line K562 contransfected with tumor-associated epithelial human mucin MUC1cDNA and with human B7cDNA (Figures 1-12) **(Current claim 1, in part; claim 5, claim 6, in part)**. Note that B7 is a cell surface costimulatory molecule in mediating interactions between T cells and APC. In addition, Ichiyama M, teaches that the population of mixed lymphocyte tumor cell culture stimulated with contransfected K562 was further incubated with Il-2 and IL-12 cytokines (Figures 1-12). Moreover, the MUC1/B7 contransfected K562 is

used as a pharmaceutical composition to stimulate, for example, growth of PBMC (p. 99, Fig. 4) **(Current claims 11 and 12, in part).**

Ichiyama M, do not specifically teach expression of glycophorin in K562.

However, at the time the invention was made, Benoist teaches that the K562 tumor cells present glycophorin A (GPA) on the cell surface. Indeed, Benoist discloses that increase of GPA expression on the cell surface may correlate with the resistance of K562 to NK cells (Abstract) (Current claim 1, in part).

The combined disclosure of Ichiyama M. and Benoist fails to teach the presence of TF in the cell line K562.

However, at the time the invention was made, Karsten discloses the presence of the TF antigen (Galβ1-3GalNAcα-O-Ser/Thr (Core 1)) and Tn antigen (GalNAcα-O-Ser/Thr) at different single and multiple positions within the immunodominat region of the MUC1 repeat (p. 2541, col. 2, paragraphs 1-2) **(Current claim 1, in part)**

The combined disclosure of Ichiyama M, Benoist and Karsten fails to teach transformation of the cell line K562 with a vector encoding at least a cytokine, MHC I, and others).

However, at the time the invention was made, Horton is an exemplified prior art that teaches that it is routine or well-established in the art to employ *ex vivo* polynucleotide constructs and selective transfection of malignant cells containing polynucleotides expressing therapeutic or prophylactic molecules (col. 1, lines 20-25) . Moreover, Horton discloses polynucleotide constructs encoding an interferon and an additional cytokine or an immunomodulatory molecule, i.e., MHC class I antigen, tumor antigen, and co-stimulatory molecule (col. 32, lines 35-45).

Horton describes examples of well known tumor-associated antigenic and immunogenic antigens, including TF and MUC1 (col. 47, lines 65-67) **(Current claim 6, in part).**

Therefore, in view of the benefits of a cancer vaccine cell line K562 that expresses MUC1/B7 after transfection with a vector encoding said molecules as taught by Ichiyama M, said cell line further comprising on the cell surface TF and glycophorin as disclosed by Benoist and Karsten, , it would have been *prima facie* obvious for one of ordinary skill in the art, as a matter of design of choice, to modify the K562 cell line by transfection with a nucleic acid encoding any epitope to enhance the immunogenic response (e.g., cellular and humoral) against said epitopes, particularly because transfection of malignant cells containing polynucleotides expressing therapeutic or prophylactic molecules was well known in the art as taught by Horton. The manipulation of previously identified DNA fragments and cell transformation systems is within the ordinary level of skill in the art of molecular biology. One of ordinary skill in the art would have had a reasonable expectation of success in generating a cell line which expresses on the surface TF, MUC1 and glycophorin and any additional nucleic acid encoding one or more polypeptides as evidenced by the production of tumor cell lines in the instant specification by following the combined teachings of Ichiyama M, Benoist, Karsten and Horton.

Conclusion

Claims 1, 3, 5, 6, 11, 12, 20 and 22 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633